This document is scheduled to be published in the Federal Register on 03/08/2016 and available online at <a href="http://federalregister.gov/a/2016-05021">http://federalregister.gov/a/2016-05021</a>, and on <a href="mailto:FDsys.gov">FDsys.gov</a>

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Survey to assess the feasibility of establishing a gynecologic specimen bank (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Goli Samimi, Program Director, Breast and Gynecologic Cancer Research Group, Division of Cancer Prevention. 9609 Medical Center Drive, MSC 9783, Bethesda, MD 20892, or call non-toll-free number (240) 276-6582, or E-mail your request, including your address to: goli.samimi@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Survey to assess the feasibility of establishing a gynecologic specimen bank (NCI), 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute is assessing the feasibility of developing a tissue bank that would include tube and ovary tissues from women undergoing surgery for benign conditions, risk reduction and early stage cancer. Collecting tissues from tubes and ovaries containing clinically unsuspected precursors or early stage cancer is challenging, especially among women that are not at increased genetic risk. However, given that many pathology laboratories have enhanced their processing protocols for gynecologic surgical specimens removed for benign indications, it may be possible to develop a tissue resource. Accordingly, we are requesting information via a survey about the volume of samples that are accessioned at different pathology laboratories, and the methods used to process these

samples. These data would provide information necessary to assess the feasibility of establishing a tissue bank for research and provide insights into the best design of a pilot study.

OMB approval is requested for 1 year. There are no costs to respondents other than their

time. The total estimated annualized burden hours are 42 hours.

Estimated Annualized Burden Hours

Category of Respondent	Form Name	Number of Respondents	Frequency of Response per Respondent	Time Per Response (in hours)	Burden Hours
Lab Managers	Survey	250	1	10/60	42
Totals		250			42

Dated:	March	2, 2016
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Karla Bailey

Project Clearance Liaison

National Cancer Institute, NIH

[FR Doc. 2016-05021 Filed: 3/7/2016 8:45 am; Publication Date: 3/8/2016]